K001608

13. 510(k) Summary

BLAINE SCARCARE PATCH® FOR THE TOPICAL MANAGEMENT OF HYPERTROPHIC OR KELOID SCARS

Contact: Target Health Inc.
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New York, NY 10165

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Sponsor: Blaine Labs, Inc.
9624 South John
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Dr. Robert Blaine

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13.1. Device Name

Blaine ScarCare Patch® is provided as follows:

a. Trade Name - Blaine ScarCare Patch®

b. Common Name - Topical silicone sheet for hypertrophic and keloid scars

c. Classification Name – 21 CFR 880.5075 ELASTIC BANDAGE

13.2. Predicate Device/ Company Names and Addresses

The predicate device is listed below with its 510(k) clearance number.

REJUVENESS™ (formerly known as Silk*Skin)	K(953420)	RichMark International Corporation 100 Saratoga Village Blvd. Ballston Spa, NY 12020

13.3. Description of Device

The Blaine ScarCare Patch® is a soft, self-adhesive, semi-occlusive sheet made from medical grade silicone with a polyurethane film backing paper and a non-siliconized polyester release paper.

The primary function of the silicone dressing is to aid in the management of both existing and new hypertrophic and keloid scars resulting from surgery, trauma and burns.

The Blaine ScarCare Patch® comes in two sizes; 2x6 inches and 3x4 inches. The sheet may be trimmed to the desired shape or size prior to placement on the scar. Also, two or more sheets can used together to cover a scar area that is greater than a single sheet.

The Blaine ScarCare Patch® is self-adhering but can also be secured by a lightly conforming bandage or tape.

The Blaine ScarCare Patch® is non-sterile and supplied in a foil patch.

13.4. Intended Use

Blaine ScarCare Patch®is intended for use in the topical management of hypertrophic and keloid scars. Do not use on open wounds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 25 2000

Blaine Labs, Inc.
c/o Dr. Robert Blaine
Target Health, Inc.
305 Madison Avenue
25th Floor
New York, New York 10165

Re: K001608
Trade Name: ScarCare Patch®
Regulatory Class: Unclassified
Product Code: MDA
Dated: May 23, 2000
Received: May 24, 2000

Dear Dr. Blaine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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5. Indication for Use

The Blaine ScarCare Patch® is intended for Over-The-Counter use for the management of old and new hypertrophic and keloid scarring on scars resulting from burns, general surgical procedures and trauma wounds.

Donna R. Lochner

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001608